EPA Registration File
2596-180

DATA EXTRACTION REQUEST

Reg # 25961-80 Decision # _____

Description: _____

_____

Material Sent:

X Electronic Label/Letter Dated 10/23/14 + CSF all (ner)
(See PPLS for electronic file)

☐ Stamped Label Dated _____ (See jacket)

☐ Notification Dated _____ (See jacket)

☐ New CSF(s) Dated _____ (See jacket)

☐ Other: _____

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Autumn Metzger

Division: RD - IRB

Phone: 305-5314

Date: 11/19/14

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	Date of Issuance:
2596-180	10/23/2014

Term of Issuance:
Conditional

Name of Pesticide Product:
Hartz Reference #145

Name and Address of Registrant (include ZIP Code):
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. This registration is time-limited and expires two years from the date this product is first released for shipment.

   You must provide the Agency with a projected release for shipment date within 30 days of the date of this Notice of Registration. The Agency will calculate the expiration date based on the projected release for shipment date until an actual release for shipment date is provided in writing.

Continued next page

Signature of Approving Official:	Date:
Venus Eagle Venus Eagle, Product Manager 01 Invertebrate-Vertebrate Branch 3, Registration Division (7505P)	10/23/2014

EPA Form 8570-6

2. Only one basic confidential statement of formula will be on file for this product at any one time; no alternate formulations or minor formulation amendments will be submitted or approved for this product.

3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning January 1, 2015.

   Please flag any Confidential Business Information (CBI) as such. Enhanced incident reporting and quarterly sales information should be submitted to the Product Manager.

   The following is a list of information that must be included in the quarterly reports for each incident:

   EPA Registration Number
   Product name (brand name)
   Lot #
   Where purchased: internet, store, veterinarian
   Active Ingredient(s)
   Weight range for product

   Date on which incident occurred. (mm/dd/yyyy)
   State in which the incident occurred. (standard 2 letter abbreviation)
   Registrant case #

   Species: dog, cat, other (specify)
   Breed: (as reported by pet owner)
   Age: months or years
   Sex: M, F, or neutered
   Weight: pounds

   Primary Route of Exposure: dermal, oral, other animal, inhalation, other
   Body System: neurological, dermatological, GI, respiratory, ocular, other
   Major signs noted with separate column for each sign, using standard terminology
   Time to Onset: (hours, days)
   Treated by veterinarian: yes or no
   First time product used: yes or no
   Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
   Any known precondition
   EPA Severity Code: death, major, moderate, minor
   Outcome: died, recovered, still treated, unknown

4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:

   a. All incidents should be reported including all minor dermal and ocular irritation reports.

b. Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

c. A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.

d. Summary table for dogs and table for cats showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).

e. A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.

f. A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label.

g. A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range.

h. Table showing number of incidents for each dog breed.

i. Table showing number of incidents in dogs for each clinical sign.

j. Table showing number of incidents in dogs for each organ system.

k. Report aggregate incidents, but do not combine moderate and minor incidents.

5. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

6. You are required to comply with the DCIs identified below:

   a. Imidacloprid GDCI-129099-951, issued on 11/10/2010
   b. Pyriproxyfen GDCI- 129032-1299, issued on 2/21/2014

If you have questions about the Generic DCIs listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://www.epa.gov/oppsrrd1/contacts_prd.htm

7. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

8. Make the following label changes before you release the product for shipment:

    - Revise the EPA Registration Number to read, "EPA Reg. No. 2596-180."

9. Submit one copy of the final printed label for the record before you release the product for shipment.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 8/28/2014

If you have any questions, please contact Autumn Metzger at (703) 305-5314 or metzger.autumn@epa.gov.

Venus Eagle, Product Manager 01
Invertebrate-Vertebrate Branch 3, Registration Division
(7505P)

Attachment – stamped label

[FRONT PANEL]
Hartz® Reference # 145

Alternate Brand Names

Hartz First Defense Max for Dogs [& *or* and Puppies]
Hartz First Defense Advanced PLUS for Dogs [& *or* and Puppies]
Hartz First Defense Advanced PRO for Dogs [& *or* and Puppies]
Hartz First Defense Evolution for Dogs [& *or* and Puppies]
Hartz First Defense Guardian for Dogs [& *or* and Puppies]
Hartz Generic Flea Topical Treatment for Dogs [& *or* and Puppies]
Hartz Generic Flea Topical for Dogs [& *or* and Puppies]
Hartz First Defense ADVANCED for Dogs [& *or* and Puppies]
Hartz ADVANCED for Dogs [& *or* and Puppies]
Hartz ADVANCE PRO for Dogs [& *or* and Puppies]
Hartz UltraGuard Sentinel MAX for Dogs [& *or* and Puppies]
Hartz UltraGuard Sentinel PLUS for Dogs [& *or* and Puppies]
Hartz UltraGuard Sentinel PRO for Dogs [& *or* and Puppies]
Hartz UltraGuard Defender for Dogs [& *or* and Puppies]
Hartz UltraShield for Dogs [& *or* and Puppies]
Hartz ImidaShield MAX for Dogs [& *or* and Puppies]
Hartz ImidaShield PLUS for Dogs [& *or* and Puppies]
Hartz ImidaShield PRO for Dogs [& *or* and Puppies]
Hartz ImidaShield II MAX for Dogs [& *or* and Puppies]
Hartz ImidaShield II PLUS for Dogs [& *or* and Puppies]
Hartz ImidaShield II PRO for Dogs [& *or* and Puppies]
Hartz ImidaGuard MAX for Dogs [& *or* and Puppies]
Hartz ImidaGuard PLUS for Dogs [& *or* and Puppies]
Hartz ImidaGuard PRO for Dogs [& *or* and Puppies]
Hartz ImidaGuard II MAX for Dogs [& *or* and Puppies]
Hartz ImidaGuard II PLUS for Dogs [& *or* and Puppies]
Hartz ImidaGuard II PRO for Dogs [& *or* and Puppies]
Hartz ProCare for Dogs [& *or* and Puppies]
Hartz FirstCare for Dogs [& *or* and Puppies]

[Each of the above brands will be packaged in the weight classes designated below:]

For use ONLY on Dogs [and Puppies] 7 weeks and older weighing 3 - 10 lbs.
or weighing 11 - 20 lbs.
or weighing 21 - 55 lbs.
or weighing over 55 lbs.

[FRONT PANEL (cont.)]

ACTIVE INGREDIENTS:

Imidacloprid	9.10%
Pyriproxyfen	0.46%
Other Ingredients.	90.44%
Total	100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for precautionary statements and directions for use.

[Large clear picture of dog in appropriate breed/weight class on front panel of product to be included]

NET CONTENTS:

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	Contains 1 tube, each 0.013 fl. oz. (0.40 ml.)
11 to 20 lbs.	Contains 1 tube, each 0.034 fl. oz. (1.00 ml.)
21 to 55 lbs.	Contains 1 tube, each 0.084 fl. oz. (2.50 ml.)
55 lbs. and Over	Contains 1 tube, each 0.135 fl. oz. (4.00 ml.)

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.039 fl. oz. (1.20 ml.), Contains 3 tubes, each 0.013 fl. oz. (0.40 ml.)
11 to 20 lbs.	0.102 fl. oz. (3.00 ml.), Contains 3 tubes, each 0.034 fl. oz. (1.00 ml.)
21 to 55 lbs.	0.252 fl. oz. (7.5 ml.), Contains 3 tubes, each 0.084 fl. oz. (2.50 ml.)
55 lbs. and Over	0.405 fl. oz. (12.00 ml.), Contains 3 tubes, each 0.135 fl. oz. (4.00 ml.)

[FRONT PANEL (cont.)]

NET CONTENTS (cont.):

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.052 fl. oz. (1.60 ml.), Contains 4 tubes, each 0.013 fl. oz. (0.40 ml.)
11 to 20 lbs.	0.136 fl. oz. (4.00 ml.), Contains 4 tubes, each 0.034 fl. oz. (1.00 ml.)
21 to 55 lbs.	0.336 fl. oz. (10.00 ml.), Contains 4 tubes, each 0.084 fl. oz. (2.50 ml.)
55 lbs. and Over	0.540 fl. oz. (16.00 ml.), Contains 4 tubes, each 0.135 fl. oz. (4.00 ml.)

For use ONLY on Dogs and Puppies 7 weeks and older Weighing:	Net Contents (Each tube)
3 to 10 lbs.	0.078 fl. oz. (2.40 ml.), Contains 6 tubes, each 0.013 fl. oz. (0.40 ml.)
11 to 20 lbs.	0.204 fl. oz. (4.00 ml.), Contains 6 tubes, each 0.034 fl. oz. (1.00 ml.)
21 to 55 lbs.	0.504 fl. oz. (15.00 ml.), Contains 6 tubes, each 0.084 fl. oz. (2.50 ml.)
55 lbs. and Over	0.810 fl. oz. (24.00 ml.), Contains 6 tubes, each 0.135 fl. oz. (4.00 ml.)

DO NOT USE ON CATS [1.5 x 1.5 cm black on yellow background]

[BACK PANEL]

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands thoroughly with soap and warm water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 7 weeks of age or weighing less than [3lbs.; 11lbs.; 21lbs.; 55lbs.] As with any product, consult your veterinarian before using this product on debilitated, aged, pregnant or nursing dogs. Individual sensitivities, while rare, may occur after using ANY pesticide product for dogs. If signs persist, or become more severe, consult a Veterinarian immediately. If your dog is on medication, consult your veterinarian before using this or any other product.

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FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For medical emergencies or consumer questions call 1-800-275-1414.

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15 – 20 minutes. Call a poison control center or doctor for treatment or advice.

[BACK PANEL (cont.)]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

READ ENTIRE LABEL BEFORE EACH USE

RESTRICTIONS

USE ONLY ON DOGS OR ON PUPPIES 7 WEEKS OF AGE OR OLDER WEIGHING [3 to 10 lbs.; 11 to 20 lbs.; 21 to 55 lbs.; Over 55 lbs.]
DO NOT USE ON OTHER ANIMALS
DO NOT EXCEED LABELED DOSAGE AMOUNT FOR DOGS
DO NOT APPLY MORE THAN ONE (1) TUBE PER TREATMENT
DO NOT HAVE CONTACT OR ALLOW CHILDREN TO HAVE CONTACT WITH TREATED AREA UNTIL COMPLETELY DRY

Side Effects: Monitor your dog after application. Side effects, although very rare, may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects (such as lethargy) occur, consult your veterinarian or call 1-800-275-1414.

[1.5 x 1.5 cm black on yellow background]

DO NOT USE ON CATS. Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian immediately.

[BACK PANEL (cont.)]

[DIRECTIONS FOR USE (CONT.)]

[APPLICATION INSTRUCTIONS:]

[Visuals Depicting How to Open Applicator Tube and Application to Animal]

[OPTION 1: for 3 to 10 lbs. or 11 to 20 lbs. packages]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. ***Do not get this product in your dog's eyes or allow your dog to ingest this product.*** Do not allow the product to run off.
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[OPTION 2: for 3 to 10 lbs. or 11 to 20 lbs. packages]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**.
3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. The dog should be standing for easy application. Part the hair on the dog's back, between the shoulder blades, until the skin is visible. Place the tip of the tube on the skin and squeeze the tube to expel the entire contents directly on the skin. ***Do not get this product in your dog's eyes or allow your dog to ingest this product.*** Do not allow the product to run off.
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[BACK PANEL (cont.)]

[DIRECTIONS FOR USE (CONT.)]

[APPLICATION INSTRUCTIONS (cont.):]

[OPTION 3: for 21 to 55 lbs. and Over 55 lbs. packages]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**. Pull cap off tube.
3. Turn the cap around and place other end of cap back on tube.
4. Twist cap to break seal, then remove cap from tube.
5. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. ***Do not get this product in your dog's eyes or allow your dog to ingest this product.***
6. Discard empty tube as described in the Storage and Disposal section.
7. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[OPTION 4: for 21 to 55 lbs. and Over 55 lbs. packages]

HOW TO APPLY

1. Remove one applicator tube from the package.
2. Hold applicator tube in an upright position **facing away from you and your pet's face and eyes**.
3. Twist dispensing tip clockwise about ½ turn while pushing down to break the tube's seal. Do not remove the dispensing tip.
4. The dog should be standing for easy application. Apply the entire contents of the tube evenly to three or four spots on the top of the back from the shoulder to the base of the tail. At each spot, part the hair until the skin is visible. Place the tip of the tube on the skin and gently squeeze to expel a portion of the solution on the skin. Do not apply an excessive amount of solution at any one spot that could cause some of the solution to run off the side of the dog. ***Do not get this product in your dog's eyes or allow your dog to ingest this product.***
5. Discard empty tube as described in the Storage and Disposal section.
6. Under normal conditions the product is effective for a month. However, in case of severe flea infestation, retreatment may be necessary earlier than four weeks. Do not re-treat more often than once every seven (7) days. After flea control is obtained, return to a monthly retreatment schedule.

[BACK PANEL (cont.)]

STORAGE AND DISPOSAL

PESTICIDE STORAGE: Store in a cool, dry place inaccessible to children and pets.

PESTICIDE DISPOSAL AND CONTAINER HANDLING:

Non-refillable container. **If empty:** Do not reuse or refill this container. Place in trash or offer for recycling if available. **If partly filled:** Call your local solid waste agency or 1-800-275-1414 for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea) experts at 1-800-275-1414 (weekdays, 9 am – 5 pm E.S.T.)

EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1

Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)

[INSTRUCTIONS FOR BLISTER PACK]

HOW TO OPEN

[OPTION 1:]

1. Being careful not to cut close to the blister cavities, take scissors and cut along dotted line.
2. Peel off the [foil] [paper] from the individual blister cavity, and take out the tube.
3. Follow application instructions.
4. Repeat steps 1 and 2 for each tube.

[OPTION 2:]

1. Separate [foil] [paper] from corner of blister package.
2. Peel back [foil] [paper] and take out the tube.

INDIVIDUAL TUBE TEXT

Insert Product name

[The appropriate size and fill volume will be correctly used on each applicable dog's weight category]

Only for Use on Dogs and Puppies 7 Weeks or Older Weighing [*insert text with weight and fill volume from a line immediately below*]

3 to 10 lbs. - 0.014 fl. oz. (0.4 ml.)
11 to 20 lbs. - 0.034 fl. oz. (1.0 ml.)
21 to 55 lbs. - 0.084 fl. oz. (2.5 ml.)
Over 55 lbs. - 0.135 fl. oz. (4.0 ml.)

9.10% Imidacloprid
0.46% Pyriproxyfen

KEEP OUT OF REACH OF CHILDREN
CAUTION
Read the Entire Label before Use
EPA Reg. No. 2596-
EPA Est. No. 2596-OH-1
(Lot No. is heat stamped in tube crimp- required number)

OPTIONAL/ALTERNATE LABEL TEXT

For use on dogs and puppies 7 weeks of age and older
(Product Name) contains Imidacloprid and (an/the) insect growth regulator *or* IGR *or* Pyriproxyfen
A single topical application remains effective for [4 weeks] [1 month]
Convenient, easy-to-apply topical solution
Convenient, easy-to-apply [and fragrance free] [monthly] [topical solution]
Once a month topical flea treatment for dogs 7 weeks of age or older
(Product Name) is indicated for the prevention and treatment of fleas on dogs 7 weeks of age and older
For the treatment and prevention of flea [and lice] infestations
One treatment prevents further flea infestations for [4 weeks] [1 month] [30 days]
Kills larval stages of fleas
Stops existing flea infestations by killing adult fleas
[Prevents] [Stops] flea eggs from hatching [or developing] [into biting adults]
Effectively breaks the flea life cycle
Effectively targets all [life] stages of [fleas]
[Kills] [Controls] all flea life stages
3-way flea protection ([kills] [controls] adults, larvae, and eggs)
[Prevents] [Stops] flea eggs [and flea larvae] from developing into [(biting) (adult)] fleas
Treatment with (Product Name) kills fleas which may cause flea allergic dermatitis [FAD] [or flea bite hypersensitivity]
Flea adulticide, larvicide, and ovicide
Kills flea eggs
Controls highly [irritating] [annoying] [flea] [insect] bites
Controls flea problems (on dogs *or* on dogs and puppies)
Provides flea protection (on dogs *or* on dogs and puppies)
Controls existing fleas and flea eggs [(plus) (and)] [prevents] future flea infestations in the home
Starts working through contact
Use flea [prevention] [protection] year-round
Contains an insect growth regulator (IGR) to kill flea eggs and prevent reinfestation
Monthly use of (Product Name) kills fleas which may cause ([flea allergy dermatitis] [flea bite hypersensitivity])
Multi-stage flea control
Prevents fleas on treated dogs from infesting (reinfesting) your home
Kills fleas which may serve as intermediate hosts for tapeworms
Kills [(biting) (chewing)] lice
For treatment and prevention of [(biting) (chewing)] lice [infestations] [on dogs *or* on dogs and puppies]
For the Prevention and Treatment of Flea and Lice Infestations on Dogs
Stops existing [(biting) (chewing)] lice infestations
Dual protection against fleas and lice
Treats, prevents and controls [(biting) (chewing)] lice [infestations]
Provides effective control of [(biting) (chewing)] lice [infestations]

Kills [(biting) (chewing)] lice and prevents further infestations
For treatment and prevention of infestations with [(biting) (chewing)] lice
Remains effective after bathing and/or swimming
Remains effective following swimming and/or shampooing
Waterproof
Remains effective after exposure to rain

Prevents (establishment of) new infestations after application

Prevents all flea stages (eggs, larvae) from developing
Prevents all flea stages (eggs, larvae, pupae) from developing
Kills fleas, flea eggs, larvae, pupae [for] [4 weeks] [1 month] [30 days]

Stays on and doesn't rub off for 1 month (*or* 4 weeks)
Kills fleas for 30 days (1 month) (4 weeks)
Stops and prevents infestations
Prevents re-infestation (reinfestation)
Prevents and controls re-infestation (reinfestations)
Eliminates fleas
Long lasting – 1 month *or* 4 weeks
Effective and convenient topical treatment
(With) patented applicator
Effective after bathing
Effective after exposure to water
Easy spot on topical applicator

Remains effective even after bathing and water immersion
(Product Name) remains effective even after bathing and water immersion

Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (*or* Advantage® II)
Contains the (same) active ingredients used in Bayer Advantage® II (*or* Advantage® II) (products)
Contains Imidacloprid and Pyriproxyfen, the active ingredients used in Bayer Advantage® II (*or* Advantage® II) (brand products)
[Product Name] is not manufactured by or distributed by Bayer. Advantage® II is a registered trademark of Bayer Healthcare LLC.

Only for dogs and puppies 7 weeks of age or older
Specially formulated for dogs and puppies 7 weeks of age or older

Kills fleas within [12] hours of application
Kills fleas on dogs within [12] hours and continues to prevent infestations for [four weeks] [1 month] [30 days]

NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose, 4th dose, 5th dose, 6th dose,
First month, second month, third month, fourth month, fifth month, sixth month
Value pack
[1] [2] [3] [4] [5] [6] month supply
[4 or 6] monthly treatment(s)
Apply monthly (every 30 days)
Convenient (easy to use) applicator
(4 or 6) Pro-cision Flo® Applicator(s) (included)
(4 or 6) Pro-glide® Applicator(s) (included)
(Pro-cision Flo® Applicator)
(Pro-Glide® Applicator)

Featuring [Pro-cision Flo®] [Pro-Glide®] Applicator (for easy application)
Direct to your dog's skin
Easy (simple) to use (handle) (apply)
Made in the U.S.A
Convenient to use

After application, the treated area may appear wet for up to 24 hours
You may bathe your dog 4 days after application
To help remind you when you last applied treatment, simply write in the date when each dose is applied:

First Dose _____
Second Dose _____
Third Dose _____
Fourth Dose _____
Fifth Dose _____
Sixth Dose _____

DOG

Metzger, Autumn

From: DJones@hartz.com
Sent: Friday, October 10, 2014 2:57 PM
To: Metzger, Autumn
Subject: RE: EPA File Symbols 2596-RIN and -RIE electronic Oct 10b
Attachments: Hartz Reference #145 Master Label 2014 Oct 10b.pdf; Hartz Reference #147 Master Label 2014 Oct 10b.pdf

Autumn,
The labels with modifications are attached below. The responses are:

Blister pack - The label was copied from a Bayer master label for an imidacloprid product. Some of our drops may be packed in them. Please note these are not CRP packs and when blisters are used the complete regulatory label text is on the outside pack. Other product versions are applicator tubes in plastic bubble covers with a heavy cardboard backing. There too the full text is on the cardboard clearly visible.

Long lasting - I added "- 4 weeks *or* 1 month"

Deleted "in the dog's environment"

Thanks again,
Dave

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Date: 10/10/2014 01:35 PM
Subject: RE: EPA File Symbols 2596-RIN and -RIE

My only question is you still have optional directions for a blister pack but I thought you said there wasn't a blister pack included.

Also, need to qualify "long lasting" claim (with 4 weeks/1 month)
And I missed the claim "Kills larval stages of fleas in the dog's environment"…need to delete the part of "in the dog's environment"

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, October 10, 2014 10:53 AM
To: Metzger, Autumn

Cc: SMcNear@hartz.com
Subject: EPA File Symbols 2596-RIN and -RIE

Good morning,
I have attached the labels modified per edits. There are two lines I retained with the within 12 hour claim. I have attached the DER for the MRIDs supporting those claims in addition to the two labels and a copy of the e-mail indicating recent agency acceptance of them. Those 12 hour claims are both at the bottom of page 11 of 12 of the attached labels. I believe I incorporated all the other edits.
The two other cat labels will be following shortly.
Thank you again for all the time and effort you put into these applications.
Sincerely,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

DOG

Metzger, Autumn

From: DJones@hartz.com
Sent: Friday, October 10, 2014 11:40 AM
To: Metzger, Autumn
Cc: SMcNear@hartz.com
Subject: RE: EPA File Symbols 2596-RIN and -RIE
Attachments: Hartz Reference #145 Master Label 2014 Oct 10a.pdf; Hartz Reference #147 Master Label 2014 Oct 10a.pdf

Autumn,
Attached are modified labels with an "a" designation for version 2 with those two lines removed.
Regards,
Dave

-4429602 - added to data matrix on 5/15/14

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Date: 10/10/2014 11:29 AM
Subject: RE: EPA File Symbols 2596-RIN and -RIE

You do not have the proper cited MRIDs for the 12 hour claim.

- yes they have proper citation now

4429602 - 01

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, October 10, 2014 10:53 AM
To: Metzger, Autumn
Cc: SMcNear@hartz.com
Subject: EPA File Symbols 2596-RIN and -RIE

Good morning,
I have attached the labels modified per edits. There are two lines I retained with the within 12 hour claim. I have attached the DER for the MRIDs supporting those claims in addition to the two labels and a copy of the e-mail indicating recent agency acceptance of them. Those 12 hour claims are both at the bottom of page 11 of 12 of the attached labels. I believe I incorporated all the other edits.
The two other cat labels will be following shortly.
Thank you again for all the time and effort you put into these applications.
Sincerely,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation

Metzger, Autumn

From: Metzger, Autumn
Sent: Thursday, October 09, 2014 3:14 PM
To: 'DJones@hartz.com'
Subject: 2596-RIE DOG spot on RE: Hartz Reference #147 Master Label 2014 Oct 4.doc
Attachments: 2596-RIE hartz spot on label imidacloprid + pyriproxyfen WITH AGENCY COMMENTS 10-9-2014.pdf

Last comments, if you can have this also back by lunch tomorrow we'll be good. Thanks!

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Wednesday, October 08, 2014 12:04 PM
To: Metzger, Autumn
Subject: Hartz Reference #147 Master Label 2014 Oct 4.doc

Hi,
I believe this is where it was to go. Please take a look and I will call very soon. I looked at the cat and just have a question about which claims to retain, in particular shampoo/water resistance.
Thanks
Dave

Metzger, Autumn

From: Metzger, Autumn
Sent: Tuesday, October 07, 2014 2:58 PM
To: 'DJones@hartz.com'
Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

And just verified you are right about being able to make the comparison claim to Bayer's Advantage II since they are both the same combos.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Tuesday, October 07, 2014 2:52 PM
To: Metzger, Autumn
Cc: SMcNear@hartz.com
Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

Good afternoon,
Thank you for the response. I have been working on the 2596-RIE today. If it is ok with you I will send it to you for review. If found acceptable I can promptly modify it to the 2596-RIN by changing the product name, the EPA file number and delete the "combustible" related section.

Sincerely,
Dave

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Cc: "SMcNear@hartz.com" <SMcNear@hartz.com>
Date: 10/07/2014 02:21 PM
Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

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Dear Mr. Jones,

Thank you for providing found reviews and other attached information. I've included my comments to your rebuttals below in blue:

1. MRID44256902 - The DER for this and the prior sequenced MRID44256901 (DER attached) shows they were

Metzger, Autumn

From: Metzger, Autumn
Sent: Wednesday, October 01, 2014 11:07 AM
To: 'DJones@hartz.com'
Subject: 2596-RIE and RIN (Hartz spot on for DOGS) Label comments
Attachments: 2596-RIE hartz spot on label imidacloprid + pyriproxyfen WITH AGENCY COMMENTS 10-1-2014.pdf

Hi Dave,

Please see attached the label comments for 2596-RIE (Dog product). We can use this for –RIN as well with the exception that RIN doesn't require the combustible language.

Let's set up a time today before 2:30 EST to go over. I'd allot 45 min.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

Please understand our confusion is based on no indication of a change of EPA OPP Policy in regard to the validity of the science for these referenced studies. We have not been able to find documentation showing the DERs were invalidated nor the test protocols have been updated. Without indication to the contrary Hartz contends these studies represent good science. We respectfully ask these all be considered to support the claims proposed for these subject labels.

I am working on modifying the label per comments. The it will be back to you early next week for review.
Thank you again for your time and consideration in these applications.

Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "DJones@hartz.com" <DJones@hartz.com>,
Cc: "SMcNear@hartz.com" <SMcNear@hartz.com>
Date: 07/31/2014 01:33 PM
Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

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Please find attached the efficacy reviews for 2596-RIN and 2596-RIE.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

acceptable to EPA. The conclusion of the attached DER states imidacloprid is effective against cat fleas, their eggs and larvae.
The attached DER was reviewing a citation of a study from 1997 in 2007, therefore the re-review is 7 years old. As stated before, the Agency does have to draw a line in the sand at some point and decide to not continue to allow citations of studies that would not be to today's standards. With that said, after discussions with other efficacy reviewers and the PM, we feel that although this study isn't up to today's standards, it is borderline enough that we'll allow the citation of it at this time.

Therefore, 44256902 can be cited to support claims against flea eggs, larvae and pupae on dogs for up to 1 month

2. MRID44256903 - The DER appears in an NPIRS search (copy attached) and is referenced in an agency Product Performance/Efficacy Review dated 2 Oct 2007 (attached). We contend it is a valid number. This data supports the shampoo resistance claim.

I am not sure why this MRID was not coming up in our system, however (based on your citation of a review) I did find the original data in Documentum and was able to review the actual data. This MRID is acceptable.

Therefore, MRID 44256903 can be cited to support claims for water immersion and shampooing (against fleas) on dogs for up to 1 month

3. MRIDs 45425101 & 45425102 - These were previously submitted in support of the other imidacloprid topical products. We ask the same consideration.

These MRIDS are of data not to any real standards of today. I do not believe they support any current claims on any products. The studies are exploratory in nature using 3 dogs (cats for -02) and attach 6 fleas to a shaved area to "examine the behavior" of the fleas.

Therefore, MRIDS 45425101 & 45425102 still do not support any claims.

Please revise your label accordingly and save this email as a record of what has been accepted.

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, October 03, 2014 4:03 PM
To: Metzger, Autumn
Cc: SMcNear@hartz.com
Subject: RE: EPA File Symbols: 2596-RIE and 2596-RIN, Updated data matrices, modified draft master labels

Good afternoon,
First thank you for sending the label with the edits and taking the time to discuss them with my on October 1. Upon reviewing the label comments with our marketing and management teams, there are concerns about the deleted claims. In response to the attached memo, we offer the following comments and observations:

1. MRID44256902 - The DER for this and the prior sequenced MRID44256901 (DER attached) shows they were acceptable to EPA. The conclusion of the attached DER states imidacloprid is effective against cat fleas, their eggs and larvae.
2. MRID44256903 - The DER appears in an NPIRS search (copy attached) and is referenced in an agency Product Performance/Efficacy Review dated 2 Oct 2007 (attached). We contend it is a valid number. This data supports the shampoo resistance claim.
3. MRIDs45425101 & 45425102 - These were previously submitted in support of the other imidacloprid topical products. We ask the same consideration.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION
OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

FEE

BARCODE No.: 419030; **DECISION No.**: 486509 **FILE SYMBOL No.**: 2596-RIN;
PRODUCT NAME: Hatrz Reference #145; **PC Code(s)**: 129099&129032; **Action Code**: R315;

DATE: **September 9, 2014**

SUBJECT: **Product Chemistry Review of Hartz Reference #145**

FROM: **Akiva Abramovitch, Ph.D.**
Technical Review Branch / RD (7505P)

THROUGH: **Shyam Mathur, Ph.D.**
Product Chemistry Team Leader
Technical Review Branch/RD (7505P)

9/11/14

TO: **Autumn Metzger/Venus Eagle, PM 1**
Insecticide-Rodenticide Branch/ RD (7505C)

INTRODUCTION:

The applicant has submitted an application for registration of a new end use product containing Imidacloprid at 9.1% and Pyriproxyfen (Nylar) at 0.46%. In support of the registration application, the registrant has submitted product chemistry data corresponding to guideline 830 series, group A & group B (MRIDs 492875-01 through 492875-03).

The CSF of the basic formulation dated August 28, 2014 (Replaces the December 1, 2013 CSF) was submitted along with the product label. TRB has been asked to determine the acceptability of the product chemistry data and the proposed CSF dated 8/28/14.

SUMMARY OF FINDINGS:

1. Name of Active Ingredient: Imidacloprid (9.1%) and Nylar/Pyriproxyfen (0.46%).

2. Has the registrant claimed substantial similarity to a registered product?

   [ ] Yes; [X] No; [ ] NA; if yes give the registration number of the cited product.

3. All the source materials for the active ingredients are derived from the registered sources: [X] Yes; [ ] No.

4. All inert ingredients have been screened by IIAB and found to be approved for the proposed labeled uses: [X] Yes; [ ] No.

BARCODE No.: 419030; **DECISION No.:** 486509 **FILE SYMBOL No.:** 2596-RIN;
PRODUCT NAME: Hatrz Reference #145; **PC Code(s):** 129099&129032; **Action Code:** R315;

5. Confidential Statement of Formula(s):

[X] Basic CSF dated August 28, 2014 (Replaces the December 1, 2013 CSF)
Alternate CSFs- None

6. Product label

a. Ingredient statement: Nominal concentration of AI listed on CSF(s) concur with product label (PR Notice 91-2).

[] Yes, if not, explain below:
Is the sub statement in compliance with PR Notice 97-6 (inert ingredient vs other ingredient)?
[] Yes; [ ] No; if not, explain below:

Metallic equivalent: [ ] Yes [X] NA;
Soluble arsenic: [ ] Yes [X] NA
Isomeric ratios: [ ] Yes [X] NA
Acid equivalent: [ ] Yes [X] NA; {name} acid equivalent = xx %

b. Health related sub statements: Product contains?

Petroleum distillate at > 10%: [ ] Yes [X] No [ ] NA
Methanol at > 4%: [ ] Yes [X] No [ ] NA
Sodium nitrate/Sodium nitrite [ ] Yes [X] No [ ] NA

c. Physical chemical hazard statement: Product label requires a statement per 40 CFR §156.78 for: flammability, explosive potential or electric insulator breakdown?
[] Yes [X] No

Flash point 169 F.

Is the sub statement in compliance with PR Notice 98-6 (Total Release Fogger)?
[] Yes, [ ] No, [X] NA, if not, explain below:

d. Label requires an additional Storage and Disposal statement:
[] Yes [X] No

BARCODE No.: 419030; **DECISION No.:** 486509 **FILE SYMBOL No.:** 2596-RIN;
PRODUCT NAME: Hatrz Reference #145; **PC Code(s):** 129099&129032; **Action Code:** R315;
7. Group A: Product Chemistry Data

TRB's determination of the acceptability for the proposed product is listed in the tables below.

Guideline No.	Study Title		Data submitted		TRB's Assessment of Data	MRID Nos.
			Yes	No		
830.1550	Product Identity & Composition		X		A	492875-02
830.1600	Description of materials used to produce the product		X		A	492875-02
830.1650	Description of formulation process		X		A	492875-02
830.1670	Discussion on the formation of impurities		X		A	492875-02
830.1700	Preliminary analysis				NA	
830.1750	Certified limits (158.350)	Standard certified Limits	X		A	492875-02
		Proposed Limits				
		Justification for wider limits				
830.1800	Enforcement analytical method		X		A	492875-03

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver Request, I = In Progress,
NA = Not Applicable; U = Upgradeable

BARCODE No.: 419030; **DECISION No.:** 486509 **FILE SYMBOL No.:** 2596-RIN; **PRODUCT NAME:** Hatrz Reference #145; **PC Code(s):** 129099&129032; **Action Code:** R315; 8. Group **B:**

Guideline No.	Study Title	Value or Qualitative Description	TRB's Assessment of Data	MRID Nos.
830.6303	Physical State	Light yellow clear liquid with a solvent like odor	A	492875-01
830.6314	Oxidation/ Reduction	Components are not expected to React with oxidizing and reducing agents	W	492875-01
830.6315	Flammability	169 F	A	492875-01
830.6316	Explodability	Not explosive	A	492875-01
830.6317	Storage Stability	A study in progress	G	
830.6320	Corrosion	A study in progress	G	
830.7000	pH	6.70	A	492875-01
830.7300	Density (units)	9.772 lb/gal	A	492875-01

A = Acceptance, N = Not Acceptable, G = Data Gap, W = Waiver request, NA =Not applicable, I= In progress, U = Upgradeable.

CONCLUSION:

TRB has reviewed the CSF(s) and product chemistry data for the proposed end use product and has concluded:

1. The proposed CSF for the basic formulation dated August 28, 2014 is acceptable.

2. The data submitted corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1650 (description of formulation process), 830.1670 (discussion on the formation of impurity), 830.1750 (certified limits), and 830.1800 (enforcement analytical method) are acceptable.

3. The registrant satisfied the Group B data requirements with the exception of the Storage Stability and Corrosion data requirements. The pH was provided as requested by the Agency and reported at 6.70 on the revised CSF.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM:

To: Autumn Metzger

From: Autumn Metzger, M.S.

Date: 10/23/2014

Subject: PRODUCT PERFORMANCE REVIEW **ADDENDUM**

EPA Reg No/EPA File Symbols: 2596-RIN, **Decision** #486509, **DP Barcode**: 419034
EPA Reg No/EPA File Symbols: 2596-RIE, **Decision** #486441, **DP Barcode:** 419024

PRIA action code: R315

Formulation Type: Spot-ons

Ingredients statement from the label with PC codes included:
Imidacloprid, 129099 (9.1%)
Pyriproxyfen 129032 (0.44%)

Application rate(s) of product and each active ingredient:

Imidacloprid-	10 lb dog = 9.42 mg/kg	20 lb dog = 11.79 mg/kg	55 lb dog = 10.71 mg/kg
Pyriproxyfen-	10 lb dog =0 .48 mg/kg	20 lb dog = 0.60 mg/kg	55 lb dog = 0.54 mg/kg

Background: ADDENDUM TO EFFICACY REIVEW DP 419034 & 419024 (A. METZGER, 7/24/2014) TO UP DATE ALLOWABLE CLAIMS

The following MRIDs are found to be acceptable for citation for the following claims:

MRID 44259601 – added to data matrix to support claim: "kills fleas within 12 hours of application on dogs."

MRID 44256902 – we will allow citation of this MRID to support claims against flea eggs, larvae and pupae on dogs for up to 1 month

MRID 44256903 – originally the MRID was not found in system so I marked it as invalid (as it was found in OPPIN), but found I found the study in documentum and company provided original review. Therefore, this MRID can be used to support water immersion and shampooing claims against fleas on dogs for up to 1 month.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM:

Date: 7/24/14

To: Venus Eagle, PM 1

From: Autumn Metzger, M.S. 7/24/14

Subject: PRODUCT PERFORMANCE REVIEW – citations of efficacy data

EPA Reg No/EPA File Symbols: 2596-RIN, **Decision** #486509, **DP Barcode**: 419034
EPA Reg No/EPA File Symbols: 2596-RIE, **Decision** #486441, **DP Barcode:** 419024

PRIA action code: R315

Formulation Type: Spot-on for dogs

Ingredients statement from the label with PC codes included:
Imidacloprid, 129099 (9.1%)
Pyriproxyfen, 129032 (0.44%)

Application rate(s) of product and each active ingredient:

Imidacloprid:	10 lb dog = 9.42 mg/kg	20 lb dog = 11.79 mg/kg	55 lb dog = 10.71 mg/kg
Pyriproxyfen:	10 lb dog = 0.48 mg/kg	20 lb dog = 0.60 mg/kg	55 lb dog = 0.54 mg/kg

Background: The registrant is applying for registration of spot on products with claims of killing/controlling adult fleas, flea eggs/larvae and lice on dogs

Summary of MRIDs:

MRID 43679609 - Supports claims: kills/controls adult fleas on dogs for 1 month (study conducted on imidacloprid)
MRID 43679610 – Supports claims: kills/controls adult flea on dogs for 1 month (study conducted on imidacloprid)
MRID 47190401 – Supports lice claims for one month (study conducted on combination of imidacloprid + pyriproxyfen)

The following MRIDs were found unacceptable:

MRID 44256902 – Study on flea eggs from dogs. Not sufficient sample size used in the study. Study design no longer acceptable. Study does not support any claims.
MRID 44256903 – Not a valid MRID number.
MRID 45425101 – Study on adult fleas on dogs. Study design is not acceptable. Study does not support any claims.
MRID 45425102 – Study on adult fleas on cat fur. Study design is not acceptable. Study does not support any claims.

Recommendations:
The cited MRIDs 43679609, 43679610 & 47190401 cumulatively support general kills/controls claims against adult fleas and lice for 1 month. This does not include Bayer's "kills fleas on dogs for 12 hour claim," flea egg/larvae claims, waterproof nor shampooing claims.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

April 17, 2014

MEMORANDUM: Companion Animal Safety for 2596-RIN

Subject:	Name of Pesticide Product:	Hartz Reference #145
	EPA Reg. No. /File Symbol:	2596-RIN
	DP Barcode:	DP 419033
	Decision No.:	486509
	Action Code:	R315
	Submission:	#945486
	E-Sub.	-
	PC Codes:	129099 (Imidacloprid: 9.1%) 129032 (Pyriproxyfen: 0.46%)
From:	Byron T. Backus, Ph.D., Toxicologist Technical Review Branch Registration Division (7505P)	Byron T. Backus April-17-2014
To:	Autumn Metzger/Venus Eagle RM 01 Insecticide-Rodenticide Branch Registration Division (7505P)	
Registrant:	HARTZ REFERENCE #145	

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
Other Ingredients:	90.44%
TOTAL	100.00%

ACTION REQUESTED: "Please see the cited studies and CSF to see if they support this new product. These studies were also submitted to support EPA File Symbol 2596-RIE..."

BACKGROUND: The material received by TRB includes a cover letter (dated December 23, 2013) from the registrant, a data matrix, a CSF, and a proposed label with the signal word CAUTION. According to the data matrix, the registrant is citing companion animal safety studies in MRIDs 45097101 and 45097102 to satisfy the 870.7200 data requirements.

COMMENTS AND RECOMMENDATIONS:

1. The companion animal safety studies in MRID 45097101 (puppy study) and 45097102 (adult dog study) were originally submitted to support the following Bayer Healthcare registrations: 11556-125 (dogs and puppies 7 weeks and older weighing 11-20 lbs; dosage rate: 0.034 fl. oz. or 1.0 mL); 11556-127 (dogs and puppies 7 weeks and older weighing 21-55 lbs: 0.085 fl. oz. or 2.5 mL); 11556-130 (dogs and puppies 7 weeks and older weighing over 55 lbs: 0.135 fl. oz. or 4.0 mL); and 11556-128 (dogs and puppies 7 weeks and older weighing 3-10 lbs: 0.014 fl. oz. or 0.4 mL). Each of these Bayer Healthcare registrations has a label declaration of 9.10% imidacloprid and 0.46% pyriproxyfen.

2. The proposed product 2596-RIN also has a label declaration of 9.10% imidacloprid and 0.46% pyriproxyfen. After a comparison of the CSFs, TRB concludes that 2596-RIN is toxicologically similar to 11556-125, 11556-127, 11556-128 and 11556-130, and that the studies in MRIDs 45097101 and 45097102 will satisfy the Companion Animal Safety study requirements for 2596-RIN.

3. According to the proposed label for 2596-RIN, the following are the proposed dosages and corresponding dog/puppy weight ranges for this product: 0.014 fl. oz. (0.4 mL): 3-10 lbs; 0.034 fl. oz. (1.0 mL): 11-20 lbs; 0.084 fl. oz. (2.5 mL): 21-55 lbs; 0.135 fl. oz. (4.0 mL): over 55 lbs.

   These dosage rates and corresponding dog/puppy weight ranges are consistent with those of the Bayer Healthcare products. However, after examining the data in MRID 45097101, it is concluded that 2596-RIN has a slightly greater (~4.1%) specific gravity than the formulation that was tested in MRID 45097101.

4. Because of the higher specific gravity, dogs would be exposed to ~4.1% more imidacloprid than from the equivalent Bayer product (the pyriproxyfen is not an issue, as the studies in MRIDs 45097101 and 45097102 were on a formulation or formulations containing 0.9% pyriproxyfen). However, from the TRB review (TXR 5001580) dated September 8, 2000 states: "Both the puppy study (MRID 45097101) and the adult dog study (MRID 45097102) have been classified as acceptable. For both studies, the lack of any indications of a consistent toxicological response following exposures (4 in each study) to 5X levels of the label-specified application rates indicates that an adequate safety margin exists for this formulation and its proposed use on puppies 7 weeks and older as well as adult dogs." Since the exposure increase to imidacloprid is less than 5%, and there were no indications of toxicity in the cited companion animal studies, TRB concludes that all CAS study

requirements (870.7200) for the registration of 2596-RIN have been satisfied by citations to MRIDs 45097101 and 45097102.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

April 9, 2014

MEMORANDUM: HARTZ REFERENCE #145 ACUTE TOXICITY STUDY DERS

Subject:	Name of Pesticide Product:	Hartz Reference #145
	EPA Reg. No. /File Symbol:	2596-RIN
	DP Barcode:	DP 419031
	Decision No.:	486509
	Action Code:	R315
	Submission:	#945486
	E-Sub.	-
	PC Code:	129099 (Imidacloprid: 9.1%) 129032 (Pyriproxyfen: 0.46%)

From: Byron T. Backus, Ph.D., Toxicologist
Technical Review Branch
Registration Division (7505P)

Byron T. Backus
April-9-2014

To: Autumn Metzger/Venus Eagle RM 01
Insecticide-Rodenticide Branch
Registration Division (7505P)

M Hasler
Team Leader
TOXICOLOGY

Registrant: HARTZ REFERENCE #145

FORMULATION FROM LABEL:

Active Ingredient(s):	by wt.
129099 Imidacloprid	9.10%
129032 Pyriproxyfen	0.46%
Other Ingredients:	90.44%
TOTAL	100.00%

ACTION REQUESTED: "Please see the cited studies and CSF to see if they support this new product. These studies were also submitted to support EPA File Symbol 2596-RIE."

BACKGROUND: The material received by TRB includes a cover letter (dated December 23, 2013) from the registrant, a data matrix, a CSF, and a proposed label with the signal word CAUTION.

COMMENTS AND RECOMMENDATIONS:

1. TRB has reviewed the five acute toxicity studies in MRIDs 49287504 through 49287508, and a request for a waiver of the inhalation study data requirement (MRID 49287509).

2. The five studies are all classified as acceptable and the inhalation study can be waived with assignment of the formulation to toxicity category IV by that exposure route.

3. The acute toxicity data requirements for the registration of 2596-RIN have been satisfied.

4. Based on the results from the acute toxicity studies, the following is the acute toxicity profile of EPA File Symbol 2596-RIN:

Oral LD50	Toxicity Category III	MRID 49287504	Acceptable
Dermal LD50	Toxicity Category IV	MRID 49287505	Acceptable
Inhalation LC50	Toxicity Category IV	--	Waived
Eye Irritation	Toxicity Category III	MRID 49287506	Acceptable
Dermal Irritation	Toxicity Category IV	MRID 49287507	Acceptable
Dermal Sensitization	Non-Sensitizer	MRID 49287508	Acceptable

5. Based on the acute toxicity profile given above, the following is the precautionary and first aid labeling for 2596-RIN as obtained from the Precautionary Labeling System:

PRODUCT ID #: **002596-00180**

PRODUCT NAME: **HARTZ REFERENCE #145**

PRECAUTIONARY STATEMENTS

SIGNAL WORD: **CAUTION**

Hazards to Humans and Domestic Animals:

Harmful if swallowed. Causes moderate eye irritation. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Avoid contact with eyes or clothing. [~~Wear protective eyewear.~~]* Wear: Long-sleeved shirt and long pants, Socks, Shoes, and gloves.

*[Protective eyewear may be specified, if appropriate].

First Aid:

If swallowed:
-Call a poison control center or doctor immediately for treatment advice.
-Have person sip a glass of water if able to swallow.
-Do not induce vomiting unless told to by a poison control center or doctor.
-Do not give anything to an unconscious person.

If in eyes:
-Hold eye open and rinse slowly and gently with water for 15-20 minutes.
-Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
-Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

6. The CSF (dated December 1, 2013) for 2596-RIN should also be reviewed and accepted by the TRB Chemistry Team.

Reviewer: Byron T. Backus, Ph.D.
Date: April 9, 2014
Risk Manager (EPA): 01

The following is the Acute Toxicity Data Evaluation Record (DER) for the acute toxicity studies (MRIDs 49287504 through 49287508) submitted in support of EPA File Symbol 2596-RIN.

1. DP BARCODE: 419033				
2. PC CODES: 129099 (Imidacloprid), 129032 (Pyriproxyfen)				
3. CURRENT DATE: April 9, 2014				
4. TEST MATERIAL: Dermal Treatment TS# 13821; containing 9.1% Imidacloprid and 0.46% Nylar (Pyriproxyfen) as active ingredients; described as a light amber liquid with a density of 1.144 g/mL.				
Study/Species/Lab Study # /Date	**MRID**	**Results**	**Tox Cat**	**Core Grade**
Acute oral toxicity / rat / Product Safety Labs, Dayton NJ / Lab Study No. 37571 / November 18, 2013; amended December 12, 2013 / OCSPP 870.1100; OECD 425	49287504	Dosages: 1040 mg/kg (1 rat); 1650 mg/kg (3 rats); 2600 mg/kg (2 rats). Both rats dosed at 2600 mg/kg died; all others survived. LD50 = 2311 mg/kg with ~95% C.L. of 1650-2600 mg/kg. At 1040 mg/kg rat was hypoactive with irregular respiration and reduced fecal volume on day 1, but recovered by day 2. At 1650 mg/kg 2/3 were hypoactive and exhibited irregular respiration, reduced fecal volume and/or hunched posture with recovery by day 2. At 2600 mg/kg both showed prone posture, irregular respiration, while one also had hypoactivity and clear ocular discharge (from p. 14 of the report this rat had clear ocular discharge at 5 hours but was dead at 4 hours); both rats were dead by day 1. Gross necropsy: no abnormalities at 1040 and 1650 mg/kg; at 2600 mg/kg extremely distended stomach, moderately distended intestines and mottled liver.	III	A

Acute dermal toxicity / rat / Product Safety Labs, Dayton NJ / Lab Study No. 37638 / December 2, 2013 / OCSPP 870.1200; OECD 402	49287505	5000 mg/kg applied to 5M & 5F rats, with 24-hr dermal exposure. No mortality or signs of systemic toxicity. One female had dermal irritation which had cleared by day 3. All gained weight days 0-7 and 7-14. There were no gross abnormalities at necropsy.	IV	A
Acute inhalation toxicity / rat /	49287509 (waiver request)	Product is a liquid with low volatility; with at most 4 mLs as a single dose applied to skin of companion animals.	IV	W
Primary eye irritation / rabbit / Product Safety Labs, Dayton NJ / Lab Study No. 37639 / December 3, 2013 / OCSPP 870.2400; OECD 405	49287506	0.1 mL instilled in right eye of each of 3 rabbits. At 24 hours all eyes were positive for corneal opacity and conjunctival irritation, and 2/3 were positive for iritis. Two eyes had completely cleared (all scores zero) on day 4, and the remaining eye was clear by day 7.	III	A
Primary dermal irritation / rabbit / Product Safety Labs, Dayton NJ / Lab Study No. 37640 / December 2, 2013 / OCSPP 870.2500; OECD 404	49287507	Each of 3 rabbits received 4-hr dermal semi-occlusive exposure to 0.5 mL test material. Maximum score of 1 for erythema, 1 for edema; PDII = 0.5; all scores zero at 24, 48 & 72 hrs.	IV	A
Dermal sensitization / guinea pig / Product Safety Labs, Dayton NJ / Lab Study No. 37641 / December 12, 2013 / OCSPP 870.2600; OECD 406	49287508	Buehler Method: 20F guinea pigs received 3 once-a-week 6-hr induction treatments to 0.4 mL undiluted test material on left side of each animal. 27 days after first induction dose 0.4 mL undiluted (HNIC) test material was applied to a site on right side; at this time an additional 10 naïve guinea pigs were also exposed to the same dose. All 30 of the exposed guinea pigs scored zero at 24 and 48 hours. Positive control substance gave appropriate response.	Not a sen-siti-zer	A

n.d. = not determined; Core Grade Key: A =Acceptable, S = Supplementary, W = Waived, U = Unacceptable, D = Data Gap

Metzger, Autumn

From: DJones@hartz.com
Sent: Monday, April 21, 2014 9:08 AM
To: Metzger, Autumn
Subject: Re: EPA File Symbols: 2596-RIE and 2596-RIN application package issues
Attachments: Data Matrix Hartz Ref 145 2014 Apr 17 signed.pdf; Data Matrix Public Hartz Ref 145 2014 Apr 17 signed.pdf; Hartz Ref 145 Formul Exempt Form 2014 Apr 21 signed.pdf

Good morning,
Attached please find the three forms below for File Symbol 2596-RIN modified as indicated. The same items for 2596-RIE will be following this morning if all goes as planned. Thank you for bringing those discrepancies to my attention.
Sincerely,
David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

From: "Metzger, Autumn" <Metzger.Autumn@epa.gov>
To: "djones@hartz.com" <djones@hartz.com>,
Date: 04/10/2014 11:55 AM
Subject: EPA File Symbols: 2596-RIE and 2596-RIN application package issues

---

Mr. Jones,

As stated on my voicemail the above mentioned packages for the corresponding products have some issues that need to be revised:

- The formulator's exemption form does not match the CSF. Please revise the imidacloprid source appropriately.

- The data matrix form was not filled out accurately. Many of the data submitted is owned by Bayer, not Hartz. Revise accordingly. In addition, add for each efficacy study cited the pest, site or claim that each will represent (i.e. adult fleas, flea eggs, water immersion claim, etc.)

Autumn Metzger
Registration Division
Office of Pesticide Programs
U.S. EPA
703-305-5314

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 10, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 30-DEC-13. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

01

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 12-30-13

Experts In-Processing Signature: B.B. Date 1-7-14 Fee Paid: Yes ✓

Division management contacted on issues No_____ Yes_____ Date _____

EPA Reg. Number: 2596-RIN	EPA Receipt Date: 12-30-13

	Items for Review			Yes	No	N/A*
1	**Application Form** (EPA Form 8570-1) signed & complete including package type			X		
2	**Confidential Statement of Formula** all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All inerts, including fragrances, approved for the proposed uses (see Footnote A)	**yes**	**no**			
			X			
3	**Certification with Respect to Citation of Data** (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	**yes**	**no**			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	**Formulator's Exemption Statement** (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			X		
5	**Data Matrix** (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	**yes**	**no**			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	**5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)**			X		
7	**Is the data package consistent with PR Notice 86-5**			X		
8	**Notice of Filing included with petitions**					X

9	**If applicable for conventional applications, reduced risk rationale**			X
10	**Required Data and/or data waivers. See Footnote C.**			
	a) List study (or studies) not included with application			

Comments:

* Submitted studies PASSED PRN 11-3 review
* Inerts not approved - See inert Status Form
* Contacted registrant on 1/10/14 to inform them of inert issues and issues with the submitted studies
* Both studies that were submitted were missing signatures on Confidentiality sheet.
* 1/10/14, registrant informed me they needed more time with the corrections. I instructed registrant to forward all future correspondence to PM
* Jacket FAILED

8M

MRID: 492875

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient.** Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or

3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;

4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or

2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or

2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUSUS, NJ 07094

RE: Application for Registration dated: 30-Dec-2013
Date Fee Payment: 23-Dec-2013
Product Name: Hartz Reference # 145
EPA Registration Number: 2596-RIN
Decision Number: D-486509

Dear Registrant:

The Agency has completed its initial contents screen of your application pursuant to Section 33(f)(4)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended the Pesticide Registration Improvement Renewal Act. The Agency has determined that your application did not pass the initial contents screen and therefore must be rejected.

Specifically, the following items were missing or improperly formatted:

Inert Issues
Inert issues were not resolved.

MRID 492875-09: Volume 9- Supplemental Information
You must include one of the two acceptable statements of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See page 8 and 13 of the Notice.

In addition, registrant was contacted on 01/10/2014 to inform them of deficiencies with application and accompanying submitted studies. The registrant emailed corrections for the accompanying studies, but they needed more time to correct the inert issues.

Furthermore, pursuant to FIFRA Section 33(b)(2)(G) the Agency must retain 25% of the registration service fee. Any future submissions to the Agency will be considered a new application and subject to the full registration service fee and another initial contents screen of all necessary fees, forms, data, and draft labeling.

If you have questions, please contact Steve Schaible (703-308-9362; schaible.stephen@epa.gov).

Sincerely,

XXXXXXXX, Director
Office of Pesticide Programs

McVearry, Emily

From: McVearry, Emily
Sent: Wednesday, January 15, 2014 8:40 AM
To: 'DJones@hartz.com'
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good Morning, Mr. Jones:

Please forward any future correspondence to the appropriate product manager, and be sure to include Stephen Schaible (schiable.stephen@epa.gov) to that correspondence as well.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: McVearry, Emily
Sent: Friday, January 10, 2014 10:09 AM
To: 'DJones@hartz.com'
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good morning,

Thank you for sending your corrections. They look great! I will insert the corrections to ensure the studies pass the preliminary screen.

Best regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: DJones@hartz.com [mailto:DJones@hartz.com]
Sent: Friday, January 10, 2014 9:29 AM
To: McVearry, Emily

Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good morning,
Thank you for bringing this to my attention. I have attached scans of Statements of Data Confidentiality Claims, signed and paginated to fit into the volume. If I need to modify them, please advise, but it is the same format as previously submitted with conventional data volumes. Always interested in improving my submissions so thank you for any recommendations.
Sincerely,

David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094
TEL: 201-271-4800 x 7414
FAX: 201-271-0357

P.S. - I have prepared pages for Hartz Ref. 147 and 148 to insert when needed. They were filed simultaneously. Thanks again.

From: "McVearry, Emily" <McVearry.Emily@epa.gov>
To: "djones@hartz.com" <djones@hartz.com>,
Cc: "Ashe, Anthony" <Ashe.Anthony@epa.gov>
Date: 01/10/2014 08:46 AM
Subject: RE: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good morning, Mr. Jones:

This email is to address an issue found in the submitted studies associated with your Amended registration of products Hartz Reference # 145/ Hartz Reference #146:

MRID 492875-09: Volume 9- Supplemental Information

- You must include one of the two acceptable statements of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See page 8 and 13 of the Notice.

MRID 492877-09: Volume 9- Supplemental Information

- You must include one of the two acceptable statements of data confidentiality claims under FIFRA 10(d)(1)(A), (B), or (C) as the second element in each study. The language of two alternative forms of the Statement of Data Confidentiality Claims, shown in Attachment 3 of PR Notice 86-5, cannot be altered. See page 8 and 13 of the Notice.

Please verify and send the corrections either by e-mail or through our secure fax line as soon as possible. If you have any questions, please do not hesitate to contact me.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825

Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

From: McVearry, Emily
Sent: Friday, January 10, 2014 7:19 AM
To: 'djones@hartz.com'
Cc: Ashe, Anthony
Subject: Submission to EPA: Products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# 2596-RIN/ 2596-RIR)

Good Morning, Mr. Jones:

This e-mail is to address an inert issue with your application for registration of products Hartz Reference # 145/ Hartz Reference #146 (EPA Reg# : 2596-RIN/ 2596-RIR):

Please review the attached document "Inert Clearance Status Form" for more detail.

Please verify and send the corrections either by e-mail or through our secure fax line. I will need the corrections by Wednesday, January 15th at 11am EST. If you have any questions, please do not hesitate to contact me.

Best Regards,

Emily A. McVearry
EPA Contractor
2777 S. Crystal Drive, S-4825
Arlington, VA 22202
Ph: (703) 347-8003
Fax: (703) 305-5060
mcvearry.emily@epa.gov

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

January 7, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-486509
EPA File Symbol or Registration Number: 2596-RIN
Product Name: HARTZ REFERENCEE # 145
EPA Receipt Date: 30-Dec-2013
EPA Company Number: 2596
Company Name: THE HARTZ MOUNTAIN CORPORATION

DAVID JONES
THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R315

NEW END-USE NON-FOOD ANIMAL PRODUCT WITH SUBMISSION OF TWO OR MORE TARGET ANIMAL SAFETY STUDIES;INCLUDES DATA AND/OR WAIVERS OF DATA FOR ONLY:;PRODUCT CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);ANIMAL SAFETY STUDIES;CHILD RESISTANT PACKAGING;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

{945486P~

This package includes the following

- ◉ New Registration
- ○ Amendment

☑ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ___

for Division

- ○ AD
- ○ BPPD
- ◉ RD

Risk Mgr. 1

Receipt No. S- 945486

EPA File Symbol/Reg. No. 2596-RIN

Pin-Punch Date: 12/30/2013

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R315

Granted: R315

Amount Due: $ 8,400

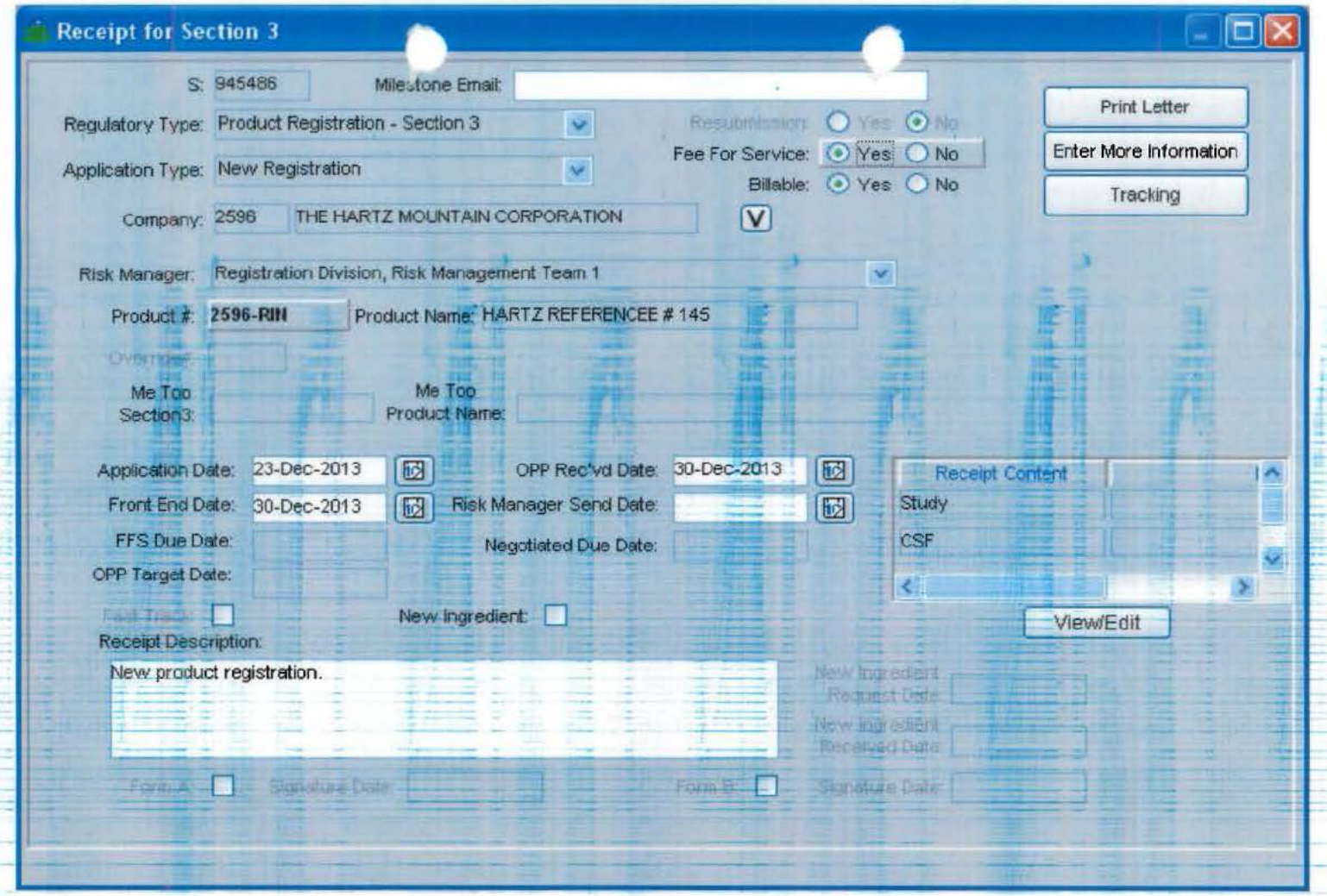
Parent/Child Decisions:

2596-RIR

☑ Inert Cleared for Intended Use ☑ Uncleared Inert in Product

Reviewer: Steve Schaible Date: 1/2/14

Remarks: - sharing acute tox, PC w/ -RIR
- citing same CAS efficacy as -RIE


Receipt for Section 3
S: 945486
Milestone Email:
Regulatory Type: Product Registration - Section 3
Application Type: New Registration
Company: 2596 THE HARTZ MOUNTAIN CORPORATION
Resubmission: Yes No
Fee For Service: Yes No
Billable: Yes No
Print Letter
Enter More Information
Tracking
Risk Manager: Registration Division, Risk Management Team 1
Product #: 2596-RIN
Product Name: HARTZ REFERENCEE # 145
Me Too Section3:
Me Too Product Name:
Application Date: 23-Dec-2013
OPP Rec'vd Date: 30-Dec-2013
Front End Date: 30-Dec-2013
Risk Manager Send Date:
FFS Due Date:
Negotiated Due Date:
OPP Target Date:
New Ingredient:
Receipt Description:
New product registration.
Receipt Content
Study
CSF
View/Edit
Form A:
Signature Date:
Form B:
Signature Date:

LIST OF DATA SUBMITTERS SENT OFFER-TO-PAY LETTERS

Application for Hartz Reference #145

Spot On Data for Products with:

Imidacloprid (Case #7605) 0.91%
Pyriproxyfen (Case #7424) 0.46%

Selective Citation Method – Only one data owner

EPA Company No. 11556
BAYER HEALTHCARE LLC
ANIMAL HEALTH DIVISION
ATTN: DR. BRUCE MARTIN
PO BOX 390
SHAWNEE MISSION, KS 66201

Hartz

THE HARTZ MOU AIN CORPORATION
400 PLAZA DRIVE
SECAUCUS, NJ 07094

No. 326829

DATE: 19-DEC-13 VENDOR NAME: US ENVIRONMENTAL PROTEC VENDOR NO: 1992

INVOICE NO	INVOICE DATE	DESCRIPTION	DISCOUNT AMOUNT	NET AMOUNT
3rd PRAS	02-DEC-13	1000086086 P- (PRIA) CODE R315	0.00	8,400.00
			0.00	8,400.00

PLEASE DETACH AND RETAIN THIS STATEMENT AS YOUR RECORD OF PAYMENT. Thank You!

THIS CHECK IS PROTECTED BY A VOID PANTOGRAPH, MICROPRINT SIGNATURE LINE AND A HEAT SENSITIVE PADLOCK ICON. ADDITIONAL SECURITY FEATURES ARE LISTED ON BACK.

Hartz

THE HARTZ MOUNTAIN CORPORATION
400 PLAZA DRIVE
SECAUCUS NJ, 07094

Bank of America

64-1278
611 GA

No. 326829

CHECK DATE	CHECK NUMBER	CHECK AMOUNT
19-DEC-13	326829	******8,400.00

PAY Eight Thousand Four Hundred Dollars And 00 Cents**********

TO THE ORDER OF
US ENVIRONMENTAL PROTECTION AGENCY
PESTICIDE REGISTRATION SERVICE FEE
PO BOX 979031
ST LOUIS, MO 63197-9000

By DR

By

Commercial/financial information may be entitled to confidential treatment

[redacted]

Please read instructions on reverse before completing form. Form Approved. OMB No. 2070-0060

Print Form

EPA

United States
Environmental Protection Agency
Washington, DC 20460

[X] Registration
[ ] Amendment
[ ] Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification
2596-	V. Eagle	[X] None [ ] Restricted
4. Company/Product (Name)	**PM#**	
HARTZ Reference #145	1	

5. Name and Address of Applicant *(Include ZIP Code)*

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

[ ] *Check if this is a new address*

6. Expedited Review. In accordance with FIFRA Section 3(c)(3)(b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____

Section - II

[ ] Amendment - Explain below.
[ ] Resubmission in response to Agency letter dated _____
[ ] Notification - Explain below.
[ ] Final printed labels in response to Agency letter dated _____
[ ] "Me Too" Application.
[X] Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New product registration. Formula and acute toxicity data identical to Hartz Reference 146 submitted simultaneously.

Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging	Unit Packaging	Water Soluble Packaging	2. Type of Container
[ ] Yes* [X] No	[X] Yes [ ] No	[ ] Yes [X] No	[ ] Metal [X] Plastic [ ] Glass [ ] Paper [ ] Other (Specify) _____
* *Certification must be submitted*	If "Yes" Unit Packaging wgt. 2 to 9 g / No. per container 1 to 10	If "Yes" Package wgt / No. per container	

3. Location of Net Contents Information	4. Size(s) Retail Container	5. Location of Label Directions
[X] Label [ ] Container	1 to 10 tubes	[X] On Label [ ] On Labeling accompanying product

6. Manner in Which Label is Affixed to Product [ ] Lithograph [ ] Paper glued [ ] Stenciled [X] Other Printed

Section - IV

1. Contact Point *(Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)*

Name	Title	Telephone No. (Include Area Code)
David Jones	Mgr. Regulatory Affairs	201.271.4800

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received (Stamped)

2. Signature	3. Title	4. Typed Name	5. Date
Dan Jones	Manager Regulatory Affairs	David Jones	12/23/2013

EPA Form 8570-1 (Rev. 8-94) Previous editions are obsolete. White - EPA File Copy (original) Yellow - Applicant Copy

THE HARTZ MOUNTAIN CORPORATION, 400 PLAZA DRIVE, SECAUCUS, NEW JERSEY 07094 201/271-4800
REGULATORY AFFAIRS

December 23, 2013

FedEx Delivery

Document Processing Desk (Distribution Code-REGFEE)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202-4501

Re: New Pesticide Product Application, Hartz Reference #145

Dear Sir/Madam,

Enclosed please find a pesticide registration application package for Hartz Reference #145. Included after the Transmittal Document are the usual and customary support materials. Hartz would like to point out that the toxicology reports are identical for the Hartz Reference #s 145 and 146 to help the Agency avoid duplicate reviews.

Enclosed is a check payable to the US Environmental Protection Agency in the amount of $8400. This is to cover the PRIA Code R315.

Direct contact by phone or e-mail is welcomed if I can assist in the processing of information presented in this package.

Sincerely,

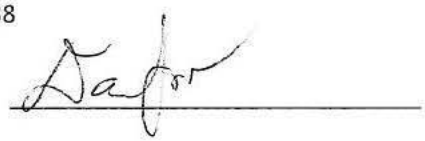
David Jones
Manager Regulatory Affairs
The Hartz Mountain Corporation
(201) 271-4800, ext. 7414
djones@hartz.com

Encl.

TRANSMITTAL DOCUMENT

Submitter:

The Hartz Mountain Corporation
400 Plaza Drive
Secaucus, NJ 07094-3688

Company Contact: 

Typed Name of Contact: David Jones

Phone: (201) 271-4800, ext. 7414

Fax: (201) 271-0357

E-mail: djones@hartz.com

Regulatory Action in Support of Which This Package is Submitted:

EPA Reg. No. 2596-___; HARTZ Reference #145; PRIA Code R315; $8400

New product application. Acute toxicology data and chemistry data are included in package. Data matrix: Selective Citations.

Submission Date:

12/23/2013

List of Submitted Documents:

Cover letter

Application Form

Confidential Statement of Formula (2 copies)

Formulator's Exemption Statement

Certification with Respect to Data with list

Data Matrix

Data Matrix, confidential public copy

TRANSMITTAL DOCUMENT

Proposed Label Text (Five copies)

PRIA Fee, Check No. for $8400.00

49287501 Volume 1 – Product Chemistry with Self-Certification

49287502 Volume 2 – Product Chemistry, Confidential Sections

49287503 Volume 3 – Product Chemistry Enforcement Analytical Method

49287504 Volume 4 – Acute Oral Toxicity

49287505 Volume 5 – Acute Dermal Toxicity

49287506 Volume 6 – Primary Eye Irritation

49287507 Volume 7 – Primary Skin Irritation

49287508 Volume 8 – Dermal Sensitization Study

49287509 Volume 9 – Data Waiver Requests

Form approved. OMB No. 2070-0060, 2070-0057, . .0-0107, 2070-0122, 2070-0164.

EPA

United States
Environmental Protection Agency
Washington, DC 20460

Formulator's Exemption Statement

(40 CFR 152.85)

Applicant's Name and Address	EPA File Symbol/Registration Number
The Hartz Mountain Corporation 400 Plaza Drive Secaucus, NJ 07094	2596-RIN
	Product Name Hartz Reference #145
	Date of Confidential Statement of Formula *(EPA Form 8570-4)* 12/01/2013

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

Imidacloprid
Pyriproxyfen

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☐ (A) An accurate Confidential Statement of Formula *(EPA FORM 8570-4)* for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☑ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source

Active Ingredient	Product Name	Registration Number
Imidacloprid Pyriproxyfen	[redacted]	[redacted]

Signature	Name and Title	Date
David Jones	David Jones/Mgr. Reg. Affairs	04/22/2014

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 – EPA
Copy 2 - Applicant copy

Product ingredient source information may be entitled to confidential treatment

Form Approved OMB Nos. 2070-0060; 2070-0057; 2070-0107; 2070-0122; 2070-0164

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number The Hartz Mountain Corp., 400 Plaza Dr., Secaucus, NJ 07094; (201) 271-4800	EPA Registration Number/File Symbol 2596-
Active Ingredient(s) and/or representative test compound(s) Imidacloprid and Pyriproxyfen	Date Dec. 23, 2013
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Indoor Use	Product Name Hartz Reference #145

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	☑ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☑ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

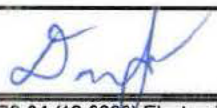
I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses .

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (I) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature	Date	Typed or Printed Name and Title
	Dec. 23, 2013	David Jones/Mgr. Regulatory Affairs

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

Date 5/15/2014	EPA Reg No./File Symbol 2596-RIN	Page 1 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #145	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identification and Composition	Submitted	The Hartz Mountain Corporation	own	
830.1600	Description of Materials Used to Produce the Product	Submitted	The Hartz Mountain Corporation	own	
830.1620	Description of the Production Process	Submitted	The Hartz Mountain Corporation	own	
830.1650	Description of the Formulation Process	Submitted	The Hartz Mountain Corporation	own	
830.1670	Discussion of Formation of Impurities	Submitted	The Hartz Mountain Corporation	own	
830.7100	Viscosity	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.1750	Certified Limits	Submitted	The Hartz Mountain Corporation	own	
830.1800	Enforcement Analytical Method	Submitted	The Hartz Mountain Corporation	own	
830.6302	Color	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6303	Physical State	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6304	Odor	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6314	Oxidation/Reduction Chemical Incompatibility	Waiver Request	The Hartz Mountain Corporation	own	
830.6315	Flammability	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6316	Explodability	Waiver Request	The Hartz Mountain Corporation	own	
830.6317	Storage Stability	To be submitted	The Hartz Mountain Corporation	own	In process

Signature	Name and Title	Date
David Jones	David Jones/Manager Regulatory Affairs	05/15/2014

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/15/2014	EPA Reg No./File Symbol 2596-RIN	Page 2 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #145	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility	Submitted	The Hartz Mountain Corporation	own	Self-Certification
830.6320	Corrosion Characteristics	To be submitted	The Hartz Mountain Corporation	own	In process
830.6321	Dielectric Breakdown Voltage	Waiver request	The Hartz Mountain Corporation	own	
830.7000	pH	Waiver request	The Hartz Mountain Corporation	own	
830.7300	Density/Relative Density/Bulk Density	Submitted	The Hartz Mountain Corporation	own	Self-Certification
870.1100	Acute Oral Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1200	Acute Dermal Toxicity	Submitted	The Hartz Mountain Corporation	own	
870.1300	Acute Inhalation Toxicity	Waiver request	The Hartz Mountain Corporation	own	
870.2400	Acute Eye Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2500	Acute Dermal Irritation	Submitted	The Hartz Mountain Corporation	own	
870.2600	Skin Sensitization	Submitted	The Hartz Mountain Corporation	own	
870.7200	Companion Animal Safety Study	45097101	Bayer Healthcare	PAY	
870.7200	Companion Animal Safety Study	45097102	Bayer Healthcare	PAY	
810.3300	Treatments to Control Pests of Humans and Pets	47190401	Bayer Healthcare	PAY	
810.3300	Treatments to Control Pests of Humans and Pets	43679609	Bayer Healthcare	OLD	

Signature	Name and Title	Date
David Jones	David Jones/Manager Regulatory Affairs	05/15/2014

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

Date 5/15/2014	EPA Reg No./File Symbol 2596-RIN	Page 3 of 3
Applicant's/Registrant's Name & Address The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094-3688	Product Hartz Reference #145	

Ingredient Imidacloprid 9.1%/ Pyriproxyfen 0.46%

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
95-9	Product Performance (Efficacy)	43679610	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	44256902	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	44256903	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	45425101	Bayer Healthcare	PAY	
95-9	Product Performance (Efficacy)	45425102	Bayer Healthcare	PAY	
95-9	Product Performance (Efficacy)	44256901	Bayer Healthcare	OLD	
95-9	Product Performance (Efficacy)	44256901	Bayer Healthcare	OLD	
810.3300	Product Performance (Efficacy)	47109101	Bayer Healthcare	PAY	
810.3300	Product Performance (Efficacy)	47298201	Bayer Healthcare	PAY	
810.3300	Product Performance (Efficacy)	48240118	Bayer Healthcare	PAY	

Signature	Name and Title	Date
David Jones	David Jones/Manager Regulatory Affairs	05/15/2014

EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only Paper version. **Agency Internal Use Copy**

Inert ingredient information may be entitled to confidential treatment

INERT CLEARANCE STATUS FORM

Reviewer Name: Emily McVearry			Request Date: 01/10/2014
Tel: (703)347-8003	ISB	CUBE: 4825	MAIL CODE:

A. COMMENTS:

~~Trade names were not found in agency database. Inert issues were not resolved. I informed the registrant to forward corrections to the product manager.~~

Approved for the intended non-food use.
D. Dobozy 1.16.14

B. PESTICIDE PRODUCT INFORMATION:

Receipt Number: 945486/ 945490 EPA Reg. No/File Symbol: 2596-RIN/ 2596-RIR Product Name: Hartz Reference # 145/ Hartz Reference #146	Date on CSF: 12/01/2013 Formulation: Basic	Food-Use Pesticide: [] Yes [x]No

C. INGREDIENT INFORMATION:

Ingredient No.1 — **Tolerance Exemption(s)[1]**

Chem. Name: [redacted]	910	920	930	940	950	960
Trade Name: [redacted]						
CAS Reg. No.: N/A						

Comments: The above ingredient [redacted] was not found in the Agency database. Please provide full compositional information including the manufacturer, constituent names, CAS numbers, and weight/weight percent composition (100% composition).

Ingredient No.2 — **Tolerance Exemption(s)[2]**

Chem. Name: [redacted]	910	920	930	940	950	960
Trade Name: [redacted]						
CAS Reg. No.: N/A						

Comments: The above ingredient [redacted] was not found in the Agency database. Please provide full compositional information including the manufacturer, constituent names, CAS numbers, and weight/weight percent composition (100% composition).

Reviewer Name: Emily McVearry **Review Date: 01/10/2014**

[1] *Language from the Code of Federal Regulations (40 CFR 180, subpart D):*
40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

[2] *Language from the Code of Federal Regulations (40 CFR 180, subpart D):*
40 CFR 180.910: Inert ingredients used pre- and post-harvest; 40 CFR 180.920: Inert ingredients used pre-harvest; 40 CFR 180.930: Inert ingredients applied to animals; 40 CFR 180.940: Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations; 40 CFR 180.950: Tolerance exemptions for minimal risk active and inert ingredients; and 40 CFR 180.960: Polymers.

Pages 68-69 - *Confidential Statements of Formula may be entitled to confidential